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*C6
cont*

19. (Amended) The medical device of claim 10 wherein the flexible composite component can be bent about 60 degrees for about 400 million cycles without significant structural failure.

20. The medical device of claim 10 wherein the composite further comprises a diamond-like carbon coating over at least a portion of the polymer.

C1 31. (Amended) The medical device of claim 1 wherein the polymer is crosslinked.

REMARKS

Claims 1-3, 5-20, and 31 are pending. The specification has been amended to correct typographical errors. Claims 10, 16-19 and 31 have been amended. A claim added in the Amendment of December 13, 2001 was inadvertently numbered as claim "21" rather than claim 31. This error has been corrected by the above amendment. The amendments of claims 10, 16, 17, 18 and 19 are intended to improve the consistency in the terminology and are not intended to change the claim scope. No new matter is introduced by the amendments.

All of the pending claims, except claim 31, presently stand rejected. Applicants respectfully request clarification of the status of claim 31. Furthermore, Applicants respectfully request reconsideration of the rejections based on the following remarks.

Rejections Under 35 U.S.C. §112, Second Paragraph, Withdrawn Rejections

In the Office Action, the Examiner withdrew earlier rejections under 35 U.S.C. §112, second paragraph. However, the Examiner indicated that Applicants had not acknowledged a reminder about elastic properties. In particular, the Examiner asserted that a crosslinked elastomer may undergo 180 degree bending and retain its (previous) elastic limit;

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and that it is the critical threshold of the amount of fatigue cycling under specific load-bearing conditions which causes the failure to maintain elastic recovery. Applicants acknowledge that crosslinked polymer can be elastic, but this issue is not relevant for most of the claims since only claim 31 recites a crosslinked polymer. Applicants believe that the idea of fatigue cycling is irrelevant to the presently claimed invention except for claims 18 and 19 that specifically recite cycle testing.

Rejection Under 35 U.S.C. §112, Second Paragraph, New Rejection

The Examiner rejected claims 1-3 and 5-9 under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner introduced this new rejection under 35 U.S.C. §112, second paragraph based on the use of the term "rigid" in amended claim 1. Applicants believe that this term is clear based on its description in the specification and the ordinary dictionary definition of the term. Applicants respectfully request reconsideration of the rejection based on the following comments.

Based on contrasts between rigid and flexible polymers and composites in the specification, the term "rigid" should be understood to mean not flexible. See, for example, the specification at page 18, lines 13-15. The term rigid in the specification is intended to take its ordinary meaning, which is well understood. The usages in the specification of the term "rigid" are consistent with the definition of "rigid" in Webster's 10th Collegiate dictionary of "deficient in or devoid of flexibility." Rigid is a commonly understood term, and the Examiner has failed to indicate what is unclear with respect to the term. Applicants believe that the Examiner has failed to establish prima facie indefiniteness with respect to the term rigid. Terms that are commonly understood by all do not need a form of measurement to define them. Thus, the term "rigid" as recited in amended claim 1 is believed to be definite as required by the statute. Applicants respectfully request withdrawal of the rejection of claims 1-3 and 5-9 under 35 U.S.C. §112, second paragraph, as being indefinite.

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Rejection Under 35 U.S.C. §102

The Examiner has maintained the rejection of claims 1-3 and 5-17 under 35 U.S.C. §102(b) as anticipated by U.S. Patent 4,778,461 to Pietsch et al. (the Pietsch patent). Applicants frame their analysis according to claim groups following the lead of the Examiner who similarly framed the response to Applicants' previous arguments. Applicants respectfully request reconsideration of the anticipation rejections based on the following comments.

With respect to claims 1-3 and 5-9, claim 1 indicates that the polymer is rigid. In contrast, the Pietsch patent discloses flexible polymers. A rigid polymer may or may not be crosslinked, and a crosslinked polymer may be rigid or flexible. While crosslinking may tend to decrease flexibility, the flexibility of a polymer will depend at least on the chemical composition, the molecular weight distribution, as well as the crosslinking density. Other polymers can be rigid without crosslinking. The claim is directed to a rigid polymer regardless of whether or not it is crosslinked. The disclosure of crosslinked polymers in the Pietsch patent does not render Applicants' claims *prima facie* anticipated. In particular, the polymers used in the leaflet of the Pietsch patent are clearly flexible since the leaflet must flex. Polymer leaflets must be flexible to open sufficiently to provide for blood flow and close sufficiently to limit backflow. Also, the leaflets must flex millions of times over its lifetime. Pietsch does not disclose rigid polymers.

With respect to claim 10, and claims 11-17 depending therefrom, it is respectfully submitted that the invention of claim 10, as amended, may be easily distinguished from the Pietsch reference. In particular, the present invention recites a **flexible composite component**. The Pietsch reference shows a heart valve but does not disclose a flexible composite component. The flexible elements in the Pietsch patent, which involve **only a polymer**, are the cusps 3, i.e., leaflets, of a heart valve as shown in figures 1 and 3. Figure 3, a cross-section, shows that a support ring 1 is present only away from the leaflet. The support ring 1 may not flex.

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In contrast, the invention of claim 10 may be readily understood by viewing Applicant's Figure 4 that depicts a leaflet with a flexible composite construction extending through the flexible portion of the leaflet. As recited in claim 10, it is the flexible composite component with both the polymer and inorganic substrate which is flexible in the present invention, not just the polymer portion of the component. Pietsch lacks such a flexible composite component and therefore does not anticipate claim 10 and claims depending from claim 10.

Based on the above discussion, the Pietsch patent does not anticipate any of Applicants' claims. Applicants respectfully request withdrawal of the rejection of claims 1-3 and 5-17 under 35 U.S.C. §102(b) as being anticipated by the Pietsch patent.

Rejection Under 35 U.S.C. §103 Over Pietsch et al.

The Examiner repeated the rejection of claims 18 and 19 under 35 U.S.C. §103(a) as being unpatentable over the Pietsch patent. The Examiner takes the position that since the Pietsch patent discloses high fatigue strength and other properties, the Pietsch patent suggests leaflets that can bend for 400 million cycles without significant structural failure. Applicants respectfully request reconsideration of the rejection over the Pietsch patent based on the following comments.

As clarified above, the claims refer to bending of the composites, i.e., inorganic substrate and polymer, and not just the bending of an individual component of the composite, such as the polymer. Therefore, the Examiner's position with respect to whether or not the polymer leaflets of the Pietsch patent would be expected to bend 400 million cycles are not on point. Specifically, Applicants noted above that the Pietsch patent does not teach or suggest a flexible composite in which both a polymer and inorganic substrate flex together. Therefore, the Pietsch patent does not have any teachings relevant to a polymer-inorganic substrate

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composite that can bend (both components of the composite simultaneously) 100 degrees without exceeding the elastic limit of the composite, i.e., the combination of the polymer and the inorganic substrate. Due to this deficiency in the Pietsch patent with respect to disclosing a flexible polymer-inorganic substrate composite, the Pietsch patent does not render claims 18 and 19 obvious. Applicants respectfully request withdrawal of the rejection of claims 18 and 19 under 35 U.S.C. §103(a) as being unpatentable over the Pietsch patent.

Rejection Over Pietsch et al. and Sumitomo Electric Co. Abstract

The Examiner also maintained the rejection of claim 20 under 35 U.S.C. §103(a) as being unpatentable over the Pietsch patent, as applied to claims 18 and 19, in view of JP abstract 59192366 to Sumitomo Electric Co. (the Sumitomo abstract). The Examiner cited the Sumitomo abstract for disclosing diamond-like carbon on a heart valve prosthesis. Applicants respectfully request reconsideration of the rejection based on the combination of the Pietsch patent and the Sumitomo abstract based on the following comments.

As noted above, the Pietsch patent does not disclose a composite with an inorganic substrate and a polymer at least partly covering the substrate that can bend 100 degrees without extending past its elastic limit. The Sumitomo abstract similarly does not teach a composite of the present claim. Since neither of the cited references teach or suggest the claimed composites, the combined disclosures of the Pietsch patent and the Sumitomo abstract does not in combination render the present invention obvious. Applicants respectfully request withdrawal of the rejection of claim 20 under 35 U.S.C. §103(a) as being unpatentable over the Pietsch patent, as applied to claims 18 and 19, in view of the Sumitomo abstract.

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CONCLUSIONS

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,



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April 10, 2002
Date

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ATTACHMENT
MARKED-UP AMENDMENTIn the Specification

Please substitute the following amended paragraph(s) and/or section(s):

At page 10, line 29-line 33:

Preferably, stent 200 has a flexibility approximating the native supporting structure of the patient's tissue. The flexibility of stent 200 can be different at different points along stent 200. Generally, ridge 212 is more rigid [that] than flexible support 214. Preferably, heart valve stent 200 is formed from the polymer/inorganic substrate composites described herein. An inorganic substrate can be located within ridge 212 and/or flexible support 214.

At page 19, line 34 to Page 20 line 4:

A variety of structural features for the medical article can be introduced into the polymer member with or without a structural basis from the inorganic substrate. Application of the polymer member tends to modify the details of the substrate, for example, by smoothing edges and filling the spaces. Furthermore, the polymer deposition process can be modified to introduce additional structure that [do] does not result from simple application of a polymer material over the surface. Appropriate processes are described further below. Suitable polymer structure for addition to the composite that does not result from the substrate include, for example, barbs, anchors, slots and/or holes for sutures and fasteners, such as pins and buttons, for attachment to a secondary assembly.

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Claims As Amended

The claims have been amended as indicated below:

10. (Twice Amended) A medical device comprising a flexible composite component comprising an inorganic substrate and a polymer member covering at least a portion of the substrate, wherein the flexible composite component can be bent at least about 100 degrees without extending the [material] flexible composite component beyond its elastic limit.

16. (Amended) The medical device of claim 10 wherein the flexible composite component can be bent about 180 degrees without extending the [material] flexible composite component beyond its elastic limit.

17. (Twice Amended) The medical device of claim 10 wherein the flexible composite component can be bent about 180 degrees with a radius of curvature of about the thickness of the composite without extending the [material] flexible composite component beyond its elastic limit.

18. (Amended) The medical device of claim 10 wherein the flexible composite component can be bent about 60 degrees for about 40 million cycles without significant structural failure.

19. (Amended) The medical device of claim 10 wherein the flexible composite component can be bent about 60 degrees for about 400 million cycles without significant structural failure.

- 31.[21.] (Amended) The medical device of claim 1 wherein the polymer is crosslinked.